

determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 02-ACE-11." The postcard will be date stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9K Airspace Designations and Reporting Points, dated August 30, 2002, and effective September 16, 2002, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

ACE KS E5 Ulysses, KS [Revised]

Ulysses Airport, KS

(Lat. 37°36'14"N., long. 101°22'24"W.)

Ulysses NDB

(Lat. 37°35'50"N., long. 101°22'05"W.)

That airspace extending upward toward from 700 feet above the surface within a 6.8-mile radius of Ulysses Airport and within 1.0 mile each side of the 306° bearing from the Ulysses NDB extending from the 6.8-mile radius to 10.5 miles northwest of the airport.

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Issued in Kansas City, MO, on October 28, 2002.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

[FR Doc. 02-28831 Filed 11-12-02; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 01-AWP-15]

Modification of Class E Airspace; Needles Airport, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies the Class E airspace area at Needles Airport, CA. The establishment of an Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) RNAV (GPS) Runway (RWY) 29 SIAP to Needles Airport, Needles, CA has made action necessary. Additional controlled airspace extending upward from 700 feet or more above the surface of the earth is needed to contain aircraft executing the RNAV (GPS) RWY 29 SIAP to Needles Airport. The intended effect of this action is to provide adequate controlled airspace for Instrument Flight Rules operations at Needles Airport, Needles, CA.

EFFECTIVE DATE: 0901 UTC January 23, 2003.

FOR FURTHER INFORMATION CONTACT: Jeri Carson, Airspace Specialist, Airspace Branch, AWP-520, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725-6611.

SUPPLEMENTARY INFORMATION:

History

On August 27, 2002, the FAA proposed to amend 14 CFR part 71 by modifying the Class E airspace area at Needles Airport, CA (67 FR 54977). Additional controlled airspace extending upward from 700 feet or more above the surface is needed to contain aircraft executing the RNAV (GPS) RWY 29 SIAP to Needles Airport. This action will provide adequate controlled airspace for aircraft executing the RNAV (GPS) RWY 29 SIAP to Needles Airport, Needles, CA.

Interested parties were invited to participate in this rulemaking, proceeding by submitting written comments on the proposal to the FAA. No comments to the proposal were received. Class E airspace designations for airspace extending from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9K, dated August 31, 2002, and effective September 16, 2002, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 modifies the Class E airspace area at Needles Airport, CA. The establishment of a RNAV (GPS) RWY 29 SIAP to Needles Airport has made this action necessary. The effect of this action will provide adequate airspace for aircraft executing the RNAV (GPS) RWY 29 SIAP to Needles Airport, Needles, CA.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; ROUTES; AND REPORTING POINTS.

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9K, Airspace Designations and Reporting Points, dated August 31, 2002, and effective September 16, 2002, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

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AWP CA E5 Needles Airport, CA [Revised]

Needles Airport, CA

(Lat. 34°45'58" N, long. 114°37'24" W)

Needles VORTAC

(Lat. 34°45'58" N, long. 114°28'27" W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of the Needles Airport; and that airspace extending upward from 1200 feet above the surface within 7.8 miles south and 11.3 miles north of the Needles VORTAC 092° and 272° radials, extending from 9.6 miles west to 20.9 miles east of the Needles VORTAC.

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Issued in Los Angeles, California, on October 24, 2002.

John Clancy,

Manager, All Traffic Division, Western-Pacific Region.

[FR Doc. 02–28829 Filed 11–12–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Gonadorelin Diacetate Tetrahydrate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for use of gonadorelin diacetate tetrahydrate solution by injection in dairy cattle for the treatment of ovarian cysts.

DATES: This rule is effective November 13, 2002.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–069 that provides for veterinary prescription use of FERTELIN (gonadorelin diacetate tetrahydrate) Injection by intramuscular or intravenous injection in dairy cattle for the treatment of ovarian cysts. Phoenix's FERTELIN Injection is approved as a generic copy of Merial, Ltd.'s CYSTORELIN, approved under NADA 98–379. ANADA 200–069 is approved as of August 26, 2002, and the regulations are amended in § 522.1078 (21 CFR 522.1078) to reflect the approval. Section 522.1078 is also being revised to reflect a current format. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on

the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subject in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.1078 is revised to read as follows:

§ 522.1078 Gonadorelin diacetate tetrahydrate.

(a) *Specifications.* Each milliliter of solution contains 50 micrograms (µg) of gonadorelin diacetate tetrahydrate.

(b) *Sponsors.* See Nos. 050604, 057926, and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle.* It is used as follows:

(1) *Amount.* 100 µg per cow as a single intramuscular or intravenous injection.

(2) *Indications for use.* For the treatment of ovarian cysts in dairy cattle.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: October 28, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–28716 Filed 11–12–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Deracoxib

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.